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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,453	12/19/2005	Mehmet Toner	25594-0002US1/MGH 2224.03	8260
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EXAMINER WARE, DEBORAH K				
ART UNIT 1651		PAPER NUMBER		
NOTIFICATION DATE 03/08/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/529,453

Applicant(s)

TONER ET AL.

Examiner

DEBBIE K. WARE

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17, 24, 25, 27, 44-46, 48-50, 70-89 and 117-130 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-17, 24-25, 27, 44-46, 48-50, 70-89 and 117-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 16-17, 24-25, 27, 44-46, 48-50, 70-89 and 117-130 are pending.

Response to Amendment

The amendment filed October 21, 2009, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 27, 2008, was filed after the mailing date of the Office Action on May 30, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-17, 25, 44-46, 48-50, 70-89, and are 117-130 rejected under 35 U.S.C. 102(e) as being anticipated by newly cited Chou et al (USP 7312085).

Claims are drawn to a method of producing a cell population enriched in a first type of cell larger than an adult, enucleated red blood cell, comprising flowing blood sample, through a channel in a microfluidic device comprising interchangeable steps of flowing the sample past obstacles in the channel, the obstacles fixed in position to obtained a first sample and then flowing the first sample past the obstacles for

preferential binding of the first type of cell in the first sample to produce an enriched population of the first type of cells.

Chou et al teach a method of producing a cell population enriched in a first type of cell larger than an adult, enucleated red blood cell, comprising flowing blood sample, through a channel in a microfluidic device comprising interchangeable steps of flowing the sample past obstacles in the channel, the obstacles fixed in position to obtained a first sample and then flowing the first sample past the obstacles for preferential binding of the first type of cell in the first sample to produce an enriched population of the first type of cells, see abstract, all lines. Note col. 13, lines 25-26, and col. 10, lines 50, 62 and 65-68 as well as lines 19-30. Further, see col. 20, lines 10-35 and specifically col. 20, lines 21-22 and col. 2, lines 32-36; col. 17, all lines; col. 31, line 12, and col. 13, line 26; and col. 34, line 60; and col. 32, lines 50-60 and col. 34, lines 55-67; col. 103, lines 60-67 and col. 104, lines 1-20.

The claims are identical to the cited disclosure and are considered to be anticipated by the teachings therein. The protrusions are clearly disclosed to be fixed in position as newly claimed and the method of Chou et al as newly cited is disclosed to be capable of being carried out passively using the obstacles and the fixed posts can be treated for preferential binding of the cells in the process of Chou et al. There is no difference between the claims and the teachings of Chou et al. Two distinct directions are disclosed to separate and enrich a cell population of a whole blood sample of which clearly anticipates a first direction and second direction to produce a first sample and to

flow the sample past the obstacles that preferentially bind a first cell type is clearly anticipated by Chou et al. Each of the claimed features are disclosed by Chou et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al, as cited and discussed above, in view of newly cited Bogart (USP 5716776) and Horne et al (USP 6974667).

Claims are further drawn to a lysis solution containing specific ingredients and also drawn to a specific binding moiety.

Chou et al is discussed above.

The claims differ from Chou et al in that these specific limitations are not disclosed.

Bogart teaches lysis solution containing bicarbonate and acetazolamide, note col. 5, lines 43-55.

Horne et al teach anti-CD36 binding moiety at col. 227, in Table 9B.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select for a method of producing a cell population enriched in a first type of cell as disclosed by Chou et al a lysis solution as disclosed by Bogart and binding moiety as disclosed by Horne et al, because these are well known in the art to serve the same function as required by the cell lysis step and preferential binding required by the method of Chou et al. Clearly these specific claimed ingredients would have been expected to provide successful results since they are well recognized for the purpose of cell lysis of red blood cells and the binding moiety, anti-CD36, is well known. Each of the claimed lysis solution and binding moiety are disclosed by the cited prior art. The claims are rendered prima facie obvious.

Response to Arguments

Applicant's arguments filed October 21, 2009, have been fully considered but they are not persuasive. The argument that the claimed method is passive is noted, however, the newly cited prior art clearly discloses that the identical method is well known and is also recognized to be passive. Further, the fixed obstacles are clearly disclosed by newly cited Chou et al. Nelson and Wang have been removed as prior art as well as the previously applied Chou reference. The previous rejection has been

removed based on Applicants' amendments, however, new art was discovered while searching the newly presented amended claims and is applied as set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44, 45, 46, 58 and 121-122 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 17, 19, 20-22 and 24 of copending Application No. 11/726,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims only differ from the copending claims in terms of the scope of the claimed subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims are drawn to a method of producing a cell population enriched in a first type of cell larger than an adult, enucleated red blood cell via flowing the sample through a device which comprises obstacles.

Copending claims are drawn to a method for producing an enriched cell population comprising a first cell type from a sample comprising two or more cell types via flowing the sample through an array of obstacles.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a method for producing a cell population enriched in a first type of cell as claimed based upon the copending claimed process for producing an enriched cell population because the methods both employ the same step of flowing through a device comprising obstacles and further because the samples to be enriched comprise the same cell types.

The copending claims would have made obvious the instant claims because the same claim features are required by each set of claims. Thus, one of skill would have been motivated to provide for the method of the instant claims based upon a reading of the copending claims with the expectation of successful results. Thus, the claims are rendered prima facie obvious over the copending claims.

Response to Arguments

The arguments filed October 21, 2009, have been received and are acknowledged but the rejection is sustained. A Terminal Disclaimer is necessary to overcome this rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
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Examiner
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